matter. While MDL Plaintiff Counsel seek to lay the problem at the defendants feet, ¹⁶ they cannot avoid their burden of demonstrating adequacy of representation of the entirety of the proposed plaintiff classes. Since such burden requires adequate representation with respect to all subclasses and all intra-class conflicts, including material variations in both the common law and statutory consumer fraud laws of the various states with differing rights of recovery by consumers, *see Relafen*, *supra*, adequate representatives must be proffered for each of these disparate interests. At a minimum, adequate representatives must be presented for the consumers in each of the States where the Attorney General has sued in order for this Court to supplant the *parens patriae* or other authority of the State Attorneys General to proceed on behalf of their citizens.

2. There Are No Adequate Representatives of the States' Claims for Declaratory and Injunctive Relief

In light of the MDL Plaintiffs' decision to drop equitable remedies in this Court, it is obvious that there are no adequate representatives of the proposed classes to ensure that these States' claims for declaratory and injunctive relief against the defendants will be adequately represented and vigorously prosecuted. In light of the clear design of the State Attorneys General to pursue such equitable remedies, including injunctions under state consumer fraud laws and other laws against the unlawful pricing, marketing and sales practices, this Court must consider the problem created by the proposal of MDL Plaintiff Counsel to permit the coextensive representation of members of the classes by the MDL Plaintiff Counsel in a case where they seek less than all the relief available to members of the proposed classes. The decision to drop equitable remedies relief should be fatal

MDL Plaintiff Counsel argue that, since it is by application of the Massachusetts choice of law rules that the consumer protection laws of the fifty (50) states must be applied to the claims of the consumer classes, therefore somehow their lack of adequate representation of the consumers in most States should somehow be excused.

to any claim by MDL Plaintiff Counsel that they can adequately represent all the interests of the members of the proposed classes.

D. <u>A CLASS ACTION IS NOT THE "SUPERIOR METHOD" FOR THE "FAIR AND EFFICIENT ADJUDICATION" OF THE CLAIMS OF THE PROPOSED CLASSES IN VIEW OF THE PENDING ACTIONS BY PENNSYLVANIA AND THE JOINDER STATES.</u>

"The final hurdle Plaintiff(s) must clear under Rule 23(b)(3) is the requirement that [they] demonstrate that a class action is a fair and efficient method for adjudicating the controversy and would be superior to other methods." Mack v. Suffolk County, 191 F.R.D. 16, 24 - 25 (D. Mass. 2000). A class action is a superior method only if no reasonable alternative exists. See, e.g., Valentino v. Carter-Wallace, Inc., 97 F.3d 1227, 1234-35 (9th Cir. 1996). Here, the standard cannot be met because Pennsylvania and certain Joinder States already have sued the Track 1 Defendants in state court. Consequently, MDL Plaintiff Counsels' ipse dixit assertions that class certification is necessary to make class members' claims financially viable is completely belied by the fact that the interests of the proposed classes are being advanced by the Attorneys General of Pennsylvania and the Joinder States. Under the circumstances of this litigation, where the Attorneys General have initiated and are independently pursuing parens patriae actions that seek redress for harm caused to their citizens, an independent, overlapping MDL action that seeks certification of a massive, nationwide class of consumers and business entities involving the same conduct and harm being adjudicated by the Attorneys General is not the "superior method" for the "fair and efficient adjudication" of the controversy under Fed. R. Civ. P. 23(b)(3). Such "co-extensive" representation of private parties is unnecessary, imprudent and unwarranted under the law. See, e.g., Commonwealth of Pennsylvania v. Budget Fuel Co., 122 F.R.D. 184, 186 (E.D. Pa. 1988) (..."where the Attorney General has exercised his authority under [the law] and filed a parens patriae action,

there is simply no reason or authority for allowing *coextensive* representative by private parties.") (emphasis supplied).

This conclusion was acknowledged by this Court to be a proper result in the *McLaughlin* decision, *infra.*, and has been reached by numerous federal courts who have been faced with the question of class certification in the face of existing representation by Attorneys General. *See McLaughlin*, 224 F.R.D. at 312 (noting that "[s]ome federal courts have denied class certification where the state Attorney General had, in fact, brought a claim on behalf of the consumers in the state.").

The cases cited by the *McLaughlin* Court warrant closer scrutiny by this Court because this case involves the very situation that was lacking in *McLaughlin*: civil class plaintiffs seeking class certification in a case where the state Attorneys General <u>have sued</u>. *Id.* at 312 ("these cases, however, do not bear on whether a court should deny certification simply because the plaintiffs *could* petition the Attorney General to bring suit on behalf of all [plaintiffs] in the Commonwealth, but where the Attorney General has not actually brought suit.") (emphasis in original). Since the more recent case, *Sage v. Appalachian Oil Co.*, 1994 W.L. 637–443 (E.D. Tenn. Sept. 7, 1994), appears to have relied exclusively upon the earlier case, *Commonwealth of Pennsylvania v. Budget Fuel Co.*, *Inc.*, 122 F.R.D. 184 (E.D. Pa. 1988), the *Budget Fuel* case should be scrutinized. However, both cases involve applications by class action plaintiffs for certification of classes pursuant to Federal Rule 23 for federal antitrust claims brought on behalf of consumers. In both cases, the Attorneys General of the respective states in which the federal court resided had instituted prior *parens patriae*

It is noteworthy that in the AWP litigation the Attorney General of Massachusetts has "actually brought suit." *See* Appendix "B."

actions against some or all of the defendants for similar unlawful conduct. In granting the Attorney General's Motion to Strike the class action allegations of the competing consumer complaint, the *Budget Fuel* Court held:

"A parens patriae action is superior to a class action as a means for adjudication of collective claims. The superiority of the parens patriae action over the class action is evidenced by the lack of any provision or requirement for court approval or certification of a parens patriae action....In addition, Rule 23(b)(3) of the Federal Rules of Civil Procedure permits class certification only where 'a class action is superior to all other available methods for the fair and efficient adjudication of the controversy.' In the case sub judice, the class action brought by [the consumer plaintiff] is not a superior alternative because the Plaintiffs in the [consumer plaintiff's] action are already ably represented by the Attorney General in the Commonwealth's parens patriae action. Although the Court is cognizant of the fact that the parens patriae provisions of § 4C of the Clayton Act were not intended to negate the Rule 23 class action, where the Attorney General has exercised his authority under § 4C and filed a parens patriae action, there is simply no reason or authority for allowing co-extensive representation by private parties.

* * *

All the court is stating is that in the situation where a State Attorney General and a private class representative seek to represent the same class members, the *parens patriae* action is superior to that of the private class action.

Budget Fuel, 122 F.R.D. at 185-86.

As noted previously, this holding was directly followed and extended by the Tennessee Eastern District Court in the *Sage* case, but in a slightly different context. In *Sage*, the District Court had denied previously the civil plaintiffs' motion for class certification in light of the pending Attorney Generals' *paren patriae* action. The Tennessee Attorney General then amended the State's complaint to add a request for class certification under Rule 23 and to have itself designated the "adequate representative" of the Class. The *Sage* Court wrote that, "[w]hile it is not clear that the

State has a superior right to bring a Rule 23 class action, the State, through the Attorney General, is clearly in a superior position to bring a *parens patriae* action against defendants on behalf of all natural persons in this state." *Sage*, 1994 WL 637443 at *1. The *Sage* Court went on to hold that, with respect to the Tennessee Attorney General's subsequent application to be appointed class representative of the same Rule 23 class that the consumer plaintiffs had sought previously, "[f]or many of the same reasons and for reasons of judicial economy, it appears that the State should be the preferred representative of a class of all persons, including non-natural persons such as business entities, that were effected by the alleged price fixing conspiracy." *Id.* at *2. Because the defendants had not had an opportunity to object to the State's request, the matter was continued to another day.

In *In re Montgomery County Real Estate Antitrust Litigation*, 1988 WL 125789 (D. Md. July 17, 1988), this primary right of Attorneys General to represent their citizens was extended to the settlement context. In the case, private plaintiffs who had settled the claims of a prior certified class of purchasers of real estate services of the defendants over a period of time from September 5, 1974 and to September 30, 1976, then sought to settle the claims of class members who purchased services from after September 30, 1976 to April 1, 1977. However, the claims of these people had been part of a pending *parens patriae* action being prosecuted by the Attorney General of Maryland. *Id.* at *1. In seeking essentially to roll in the Attorney General's claims to effectuate a complete settlement, the class plaintiffs simply agreed with defendants to settle all claims involving the defendants' conduct over the entire period of the alleged conspiracy, including all conduct that fell within the period implicated in the Attorney General's action, but without consultation with or the assent of the Attorney General. *Id.*

The precise issue before the court was "whether a full settlement of this litigation can take place in the absence of assent by the Attorney General." *Id.* The court held that such a settlement could not take place, and it refused to extend the class certification beyond the prior certified period, thereby preserving the Attorney General's sole representation of natural persons in its *parens patriae* action. *Id.* at *3. The court explained that to permit otherwise would "run afoul" of Rule 23(b)(3)'s superiority requirement. *Id.* at *2. The court ruled that the class action device was not a superior method of adjudication because of the Attorney General's existing representation of the claims. *Id.* In so ruling, the court stated:

there is simply no reason or authority for allowing coextensive representation by private parties. The *parens patriae* action is plainly superior to the class action as a mode for adjudication of collective claims. A clear indication of this is the lack of any provision or requirement for court approval or certification of a *parens patriae* action.

Id. (citing 15 U.S.C. § 15(c)(b)(1)).

While the court in *In re Montgomery* dealt with this issue solely in the context of the Sherman Act, and expressly avoided the question of whether such "preemption" would be permissible outside of that context, *see id.* at n.5, the rationale supporting the court's decision applies equally here. Indeed, the court relied on the "analogous situation" presented in a non-antitrust case, *United States v. City of Chicago*, 411 F.Supp. 218, 243 (N.D. Ill. 1976), *aff'd in part, rev'd in part*, 549 F.2d 415 (7th Cir. 1977), wherein that court denied class certification for private plaintiffs in a civil rights case because the federal government already represented the proposed class members, thereby precluding satisfaction of Rule 23(b)(3)'s superiority requirement. *In re Montgomery* at *2. *See also Barcelo v. Brown*, 78 F.R.D. 531, 534 (1978) (relying on *City of Chicago* in ruling that class

action involving private plaintiffs would not be superior method for adjudication under Rule 23(b)(3) where "Commonwealth [of Puerto Rico] Plaintiffs" provided "viable alternative to coping with the difficulties inherent in the class action device.").

As an additional basis for its ruling, the court in *In re Montgomery* found that, even if it were proper as a matter of law to extend the class certification, it would have been improper to do so as a matter of fact. The court stated that the "overlapping representation... would create very serious problems" with respect to class notice and confusion of class members about their rights and options. *In re Montgomery* at *2.

This rationale of the court in *In re Montgomery* applies fully in the instant matter. The proposed class action on behalf of private plaintiffs is not the superior method of adjudication under Rule 23(b)(3) in light of the prior pending Attorney General actions. Moreover, given the pending Attorney General actions, certification of an overlapping class action is likely to cause significant confusion, whether or not the private plaintiff action, if certified, is settled or tried to verdict. Accordingly, this Court should refrain from granting nationwide class certification, and should defer to the Attorney General actions as the "superior" methods of adjudicating the claims of those who allege harm from the defendants' conduct. At a minimum, a carve out of the States is warranted.

While the States and Defendants surprisingly agree that the class action is not the "superior" litigation device, Defendants tip their hands as to their bias in wanting no case at all by arguing that there is a lack of superiority, but with no reasonable alternative. They fail to offer a reasonable alternative because the Defendants know full well that the millions of cases they say should be filed instead likely will never materialize because of the cost prohibitive nature of consumer claims. Instead, Defendants know that defeating nationwide class certification means the effective end of

the litigation against them. Consequently, this Court should adopt the reasonable middle ground approach for the litigation offered by the Attorneys General, by deferring to the state-court cases either completely or in part (by carving out Pennsylvania and the other litigating States from the proposed Classes).

III. <u>CONCLUSION</u>

For the foregoing reasons, the Commonwealth of Pennsylvania, by and through its Office of the Attorney General, along with all of the States Attorneys General who have joined in this Memorandum, respectfully requests this Honorable Court to deny plaintiffs' Motion for Class Certification.

Respectfully submitted,

Dated: February 8, 2005

Donald E. Haviland, Jr., Esquire

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FOR THE COMMONWEALTH OF PENNSYLVANIA

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EXHIBIT "A"

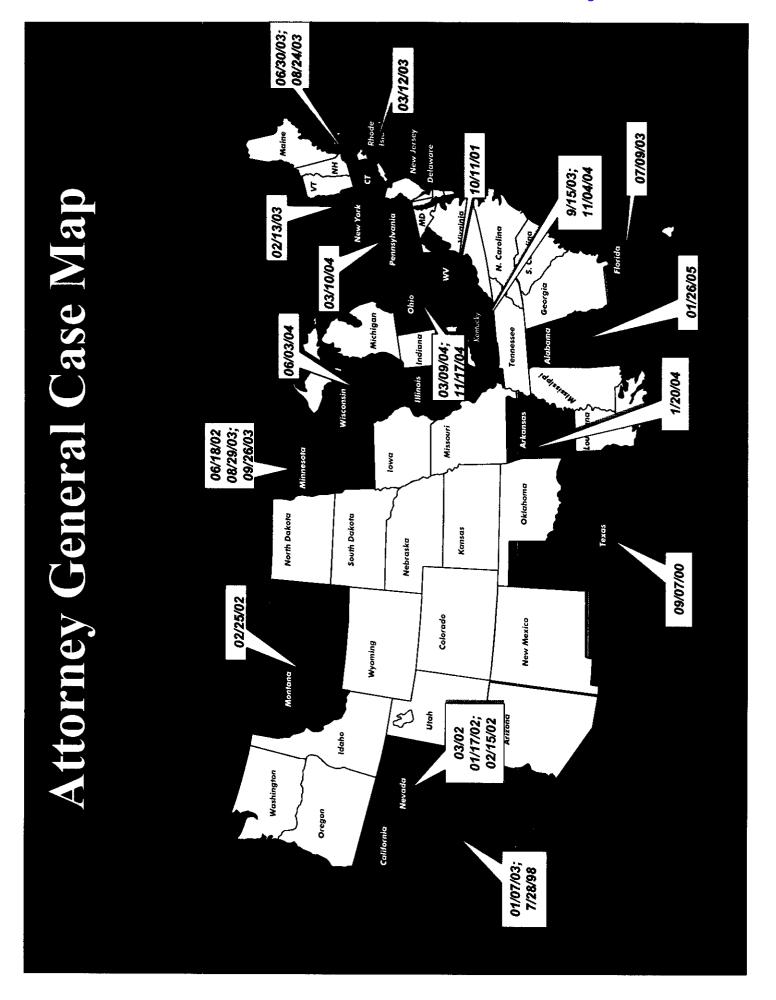


EXHIBIT "B"

Page 1

SUMMARY OF STATE LITIGATIONS

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Agouron ratories, Inc.; Alza Corporation; entis and 1-200 a on behalf rida Keys, peutic C; Aventis althcare edford Lipha, SA; teva Sor Corporation;	Other Defendants Laboratories; Agour Uticals, Inc. Alcon Laboratories, Inc.; Alpharma, Inc.; Ali on; Amgen, Inc.; Andrx Corporatio armaceuticals, Inc.; Aventis adv State of California on behalf c, Ven-a-Care of the Florida Keys, boratories; Alpha Therapeutic on; Aventis Behring, LLC; Aventis seuticals, Inc.; Baxter Healthcare on; B. Braun McGaw; Bedford ies; Dey, LP; Dey, Inc.; Lipha, SA; kins Sinn/Lederele; Geneva auticals, Inc.; Immunex Corporation ooratories, Inc.; Immunex Corporation ooratories, Inc.; Mylan auticals, Inc.; Novartis	Abbott Laboratories; Agouron Parmaceuticals, Inc.; Alza Corporation; Andrx Corporation; Andrx Pharmaceuticals, Inc.; Aventis Corporation; Andrx Pharmaceuticals, Inc.; Aventis Dey, Inc. Abbott Laboratories; Wyeth, Inc.; and 1-200 John Does adv State of California on behalf of Relator, Ven-a-Care of the Florida Keys, Inc. Abbott Laboratories; Alpha Therapeutic Corporation; Aventis Behring, LLC; Aventis Pharmaceuticals, Inc.; Baxter Healthcare Corporation; B. Braun McGaw; Bedford Laboratories; Dey, LP; Dey, Inc.; Lipha, SA; Merck; Elkins Sinn/Lederele; Geneva Pharmaceuticals, Inc.; Immunex Corporation; Mylan Laboratories, Inc.; Immunex Corporation; Pharmaceuticals, Inc.; Immunex Corporation; Pharmaceuticals, Inc.; Mylan Pharmaceuticals, Inc.; Novartis		× × Schering	X X J&J	X X J&J	X X BMS X X GSK X X J&J Schering
als Corp.; Pharmacia, Inc.; Upjohn, Inc.; Roxane Inc.; adv Peralta, by and	eurcais Corp.; Pharmacia a & Upjohn, Inc.; Roxane ies, Inc.; adv Peralta, by a	Friarmaceuticals Corp.; Pharmacia, Inc.; Pharmacia & Upjohn, Inc.; Roxane Laboratories, Inc.; adv Peralta, by and through Ibarra	Pharmaceuticals Corp.; Pharmacia & Upjohn, Inc. Laboratories, Inc.; adv Pathrough Ibarra	Pharmaceuticals Corp.; Pharmacia & Upjohn, Inc. Laboratories, Inc.; adv Ptthrough Ibarra	Pharmaceuticals Corp.; Pharmacia & Upjohn, Inc. Laboratories, Inc.; adv Ptthrough Ibarra	Pharmaceuticals Corp.; r Pharmacia & Upjohn, Inc Laboratories, Inc.; adv Puthrough Ibarra	Pharmaceuticals Corp.; r Pharmacia & Upjohn, Inc. Laboratories, Inc.; adv P. through Ibarra

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SUMMARY OF STATE LITIGATIONS

		
ATTORNEYS		
CLAIMS		
CASE NO./ COURT	CV-03-0824416-S/ Hartford Superior Court CV-03-0824413-S/ Hartford Superior Court CV-03-0824414-S/ Hartford Superior Court CV-03-0824415-S/ Hartford Superior Court	98-3032-A/ Leon Circuit Court
Other Defendants	Dey, Inc.; Roxane; Pharmacia Corp.; Pharmacia Corp.; Aventis Pharmaceuticals, Inc.	Boehringer Ingelheim, Ben Venue 98-30. Laboratories; Bedford Laboratories; Roxane; Court adv. State of Florida on behalf of Relator, Ven-a-Care of the Florida Keys, Inc.; Dey, Inc.; adv. State of Florida on behalf of Relator, Ven-a-Care of the Florida Keys, Inc.
Schering	×	×
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DATE	3/13/03	7/9/03
STATE	Connecticut* 3/13/03	Florida*

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SUMMARY OF STATE LITIGATIONS

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ATTORNEYS	OFFICE OF THE ATTORNEY GENERAL: Janet Graham, Robert Jones, Todd Leatherman, Pamela Murphy, David Johnstone, Paula Holbrook, Connie Malone. Outside Counsel: Charles Barnhill, William Dixon, Elizabeth Eberle, MINER BARNHILL & GALLAND, Madison WI; George Galland, Judson Miner, Robert Libman, Marni Willenson, MINER BARNHILL & GALLAND, Chicago IL; Jeffrey Archibald, ARCHIBALD LAW OFFICES, Madison WI.
4	OFFICE OF ATTORNEY GENERAL: Graham, Ro Todd Leathe Pamela Mur Johnstone, C Holbrook, Co Malone. Ou Counsel: Ch Barnhill, Will Elizabeth Eb MINER BAR GALLAND, N Willenson, Mar Willenson, Mar Willenson, Mar Willenson, Mar Willenson, Mar Willenson, Mar Willenson, Mar Willenson, Mar Willenson, Mar Willenson, Mar OFFICES, M
CLAIMS	Brought under parens patriae authority alleging violation of Consumer Protection Act, False Advertising statute, Medicaid fraud statute and common law fraud by defendants' inflating of AWP to increase "spread." Medicaid fraud statute and Counsel: Charles patriae authority alleging violation of Consumer Brought under parens patriae authority alleging violation of Consumer AWP to increase "spread." MINER BARNHILL Advertising statute, Advertising statute, Brought under parens Brought under
CASE NO./ COURT	03-CI-1134/ Franklin Circuit Court, Div II 03-CI-1135/ Franklin Circuit Court, Div II 04-CI-1487/ Franklin Circuit Court, Div I
Other Defendants	Abbott Laboratories, Inc.; Dey, Inc.; Abbott Laboratories, Inc.; Awentis Alpharma, Inc.; Awgen, Inc.; Aventis Pharmaceuticals, Inc.; Aventis Behring, LLC; B.Braun of America, Inc.; Baraun McGaw; International, Inc.; Bayer Corporation; Ben Circuit Court, Div I Venue Laboratories, Inc.; Boehringer Ingelheim Pharmaceuticals, Inc.; Porest Laboratories, Inc.; Immunex Corporation; Ivax Corporation; Ivax Pharmaceuticals, Inc.; Moveli-PPC, Inc.; Merck & Company, Inc.; Mylan Laboratories, Inc.; Mylan Pharmaceutical Companies, Inc.; Prizer, Inc.; Pharmaceutical Companies, Inc.; Prizer, Inc.; Pharmaceutical Products, Inc.; Pharmaceutical Co.; Roxane Laboratories, Inc.; TAP Pharmaceutical Industries, Ltd.; Watson Pharma, Inc.; Watson Pharmaceuticals, Inc. Pharmaceuticals, Inc.
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DATE	9/15/2003
STATE	Kentucky

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SUMMARY OF STATE LITIGATIONS

	T				
ATTORNEYS	OFFICE OF THE ATTORNEY GENERAL, Medicaid Fraud Control Unit: Nicholas Messuri, Robert Patten, Richard Heidlage.				
CLAIMS					
CASE NO./ COURT	C.A. No. 03-11865 PBS (D.Mass.)	MC-02-009660/ Hennepin County District Court MC-03-14691/ Hennepin County District Court	USDC D.Mass.	CV-00260/ Washoe County District Court	905-03/ Supreme Court of New York 1150-03/ Supreme Court of New York 101588/02/ Supreme Court of New York
Other Defendants	Barr Laboratories, Inc.; Dey, Inc.; Duramed Pharmaceuticals, Inc.; Ethex Corporation; Ivax Corporation; Mylan Laboratories, Inc.; Par Pharmaceutical, Inc.; Purepac Pharmaceutical Co.; Roxane Laboratories, Inc.; Schein Pharmaceutical, Inc.; Teva Pharmaceuticals USA, Inc.; Watson Pharmaceuticals, Inc.			Abbott Laboratories, Inc., et al.	Aventis Pharmaceuticals, Inc. adv. National Asbestos Workers Med. Fund
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DATE	8/24/03	9/26/03		2/15/02	
STATE	Massachusett 8/24/03	Minnesota*	Montana*	Nevada*	New York*

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SUMMARY OF STATE LITIGATIONS

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STATE	DATE	ZΑ	SW8	егк	าชา	Schering	Other Defendants	CASE NO./ COURT	CLAIMS	ATTORNEYS
Орію	3/9/04					×	Abbott Laboratories, Inc.; Dey, Inc.; Pharmacia Corp.; Ben Venue Laboratories, Inc.; Boehringer Ingelheim Corp.; Boehringer Ingelheim Pharmaceuticals, Inc.; Roxane Laboratories, Inc.	Case No. A0409296	Filed under Consumer Sales Practices Act, Deceptive Trade Practices Act, Medicaid Fraud Statute, Anti-Kickback Statute*	OHIO ATTORNEY GENERAL, Health Care Fraud Section: Drew Duffy, John Guthrie. Outside Counsel: Stanley Chesley, Fay Stilz, Robert Heuck, WAITE, SCHNEIDER, BAYLESS & CHESLEY CO, Cincinnati OH; Michael Barrett, Stephanie Bowman, BARRETT & WEBER, Cincinnati OH; James Swaim, Richard Hempfling, FLANAGAN, LIEBERMAN, HOFFMAN & SWAIM, Dayton OH; David Ewing, GARDNER, EWING & SOUZA, Louisville KY; W.B. Markovitz, MARKOVITS & GREIWE Co, Cincinnati OH.
Pennsylvania* 3/10/04	3/10/04	×	×	×	×	×	Amgen; Aventis; Baxter; Bayer; Boehringer Ingelheim Corp.; Dey, Inc.; TAP Pharmaceuticals			

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SUMMARY OF STATE LITIGATIONS

STATE	DATE	Z∀	SM8	егк	ገ&ገ	Schering	Other Defendants	CASE NO./ COURT	CLAIMS	ATTORNEYS
Texas	00/20/60						Abbott Laboratories, Inc.; Baxter Healthcare Corporation; B. Braun Medical, Inc. (formerly McGaw, Inc.); Ben Venue Laboratories, Inc.; Boehringer Ingelheim Pharmaceuticals, Inc.; Roxane Laboratories, Inc.; Hospira, Inc. adv State of Texas on behalf of Relator, Ven-a-Care of the Florida Keys, Inc.		- 15 S	Texas Attorney General: Raymond Winter, Patrick O'Connell, Michael Winget-Hernandez. For the Relator: Jim Breen, John Clark,
West Virginia*						×		01 c 3011/ Kanawha County Circuit Court		
Wisconsin	06/03/04	×	×	×	×	×	Abbott Laboratories; Amgen Inc.; Aventis Behring, LLC; Aventis Pharmaceuticals, Inc.; Baxter International, Inc.; Bayer Corporation; Bax Venue Laboratories, Inc.; Bayer Corporation; Ben Venue Laboratories, Inc.; Boehringer Ingelheim Corporation; Boehringer Ingelheim Pharmaceuticals, Inc.; Dey, Inc.; Immunex Corporation; Ivax Corporation; Ivax Corporation; Ivax Pharmaceuticals, Inc.; Merck & Company, Inc.; Mylan Laboratories, Inc.; Mylan Pharmaceuticals, Inc.; Novartis Pharmaceuticals, Inc.; Pharmaceuticals, Inc.; Pharmaceuticals, Inc.; Pharmaceuticals, Inc.; Sandoz, Inc.; Sicor Pharmaceuticals, Inc.; Stoor Pharmaceuticals, Inc.; Teva Pharmaceutical Products, Inc.; Teva Pharmaceutical Industries, Ltd.; Watson Pharma, Inc.; Watson Pharma, Inc.;			Wiscon Dept of Justice: Michael Bauer, Cynthia Hirsch, Frank Remington. Outside Counsel: Charles Barnhill, William Dixon, Elizabeth Eberle, MINER BARNHILL & GALLAND, Madison WI; Jeff Archibald, ARCHIBALD CONSUMER LAW OFFICES, Madison WI.
*Information obtained from NAAG or MDL	btained fro	Ψ W W	AG or		ase hi	story	case history websites.			

EXHIBIT "C"



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MONDAY, APRIL 2, 2001

SPECIAL REPORT: States Mull Suit Against Drug Companies

By Mary Guiden, Staff Writer, Stateline.org

In an action modeled on their 1998 class action lawsuit against the tobacco industry, at least six states are poised to go to court to try to force pharmaceutical companies to lower prescription prices, law enforcement and health care officials tell Stateline.org.

"The goal is nothing less than changing the way the industry does business," says Mark Schlein, director of Florida's Medicaid Fraud Control Unit in the Attorney General's office.

Attorneys general in Florida, Georgia, Maine, Massachusetts, Nevada and Texas are among those considering legal action, officials from some of the offices said. Nevada's Tim Terry, director of the state's Medicaid Fraud Control Unit, says while he's "not at liberty to comment" on specifics, he expects "other developments [on this matter] in the next couple of months."

A state health official familiar with discussions about state action said there's a strong consensus across the country. "I really get the sense there's a lot of energy, mostly from attorney generals' offices. As soon as there's any kind of endorsement from the Health Care Financing Administration (HCFA), all 50 states are going to jump on it," said the official, who spoke on condition of anonymity.

HCFA, the federal agency that oversees Medicaid and Medicare, requires drug manufacturers to report their lowest drug prices, or "best price." "We've asked for their assistance to determine whether or not pharmaceutical manufacturers violated agreements with HCFA to provide states with the best price on drugs," says Martin Smith, spokesperson for Georgia's Department of Community Health.

A HCFA spokesperson declined comment on any potential problems.

State attorneys general aren't waiting for HCFA's permission to seek information from the drug companies. Bristol-Meyers Squibb says it and other manufacturers have responded to subpoenas from Massachusetts and several other states.

"We have cooperated fully with the subpoenas, and we're not aware we're the subject of any investigation. Bristol-Meyers is not the only company being investigated in an attorney general's office. We're confident that our practices are fully compliant with state and federal laws," says spokesperson Patrick Donahue.

The potential for litigation grows out of a three year-old Justice Department investigation of the Bayer Corporation that in January resulted in Bayer settling with the states and the federal government for \$14 million.

In a Jan. 23 news release announcing the settlement, the Justice Department said the government's investigation "revealed that the pharmaceutical company beginning in the early 1990s falsely inflated the reported drug prices referred to by the industry as the Average Wholesale Price."

The AWP is the average price that wholesalers give to retailers for a given medication. Medicare and Medicaid programs use the AWP in calculating reimbursements to pharmacists and doctors.

"By setting an extremely high AWP and, subsequently, selling the product to doctors at a dramatic discount, Bayer induced physicians to purchase its products rather than those of competitors by enabling doctors to profit from reimbursement paid to them by the government," the Justice Department said. As part of the agreement, Bayer said it would "provide the state and federal governments with the average selling prices of its drugs ... and potentially prices for its competitors' products," the Justice Department said.

Meantime, Texas Attorney General John Cornyn brought a lawsuit against three drug companies seeking \$79 million for alleged Medicaid fraud. The firms are Dey, Inc., Roxane Laboratories, Inc. and Warrick Pharmaceuticals Corp.

In court documents filed by the state in Travis County District Court on Sept. 7, the suit says that the firms "knowingly and intentionally made false representations of prices and costs for certain of their inhalation drugs directly and indirectly to the Texas Medicaid program."

The state also says the "Medicaid program relied on the false and deceptive inflated prices and costs reported by the [pharmaceutical companies] and thus was defrauded into paying amounts that substantially exceeded a true and correct price for the drugs in question." Justice Department spokesperson Jill Stillman and Barbara Zelner, a spokesperson for the National Association of Medicaid Fraud Control Units, refused to comment on inquiries into other manufacturers, citing an "ongoing investigation." The Pharmaceutical Research and Manufacturers of America (PhRMA)-which drug companies defer to--also refused comment, citing the "ongoing" nature of the case.

A catalyst for state legal action is Florida businessman Zachary Bentley, who is going from state to state urging state attorneys general to sue drug manufacturers. It was Bentley who triggered the Bayer case. He says he alerted federal authorities years ago about "the corrupting influence" of pharmaceutical manufacturers after his healthcare company was "put out of business" by a competitor. Under whistleblower and federal False Claims laws, Bentley gets a portion of any settlement that results from what he's revealed.

Through his company, which delivered intravenous drugs for diseases like AIDS to a patient's home, Bentley says he discovered discrepancies between the published Average Wholesale Price (AWP) of prescription drugs and what the drug companies actually charged retailers for the same drugs. "Medicaid and Medicare reimburse certain drugs at ten times the cost. Providers, as a result, make a huge windfall profit," Bentley says.

Because of Bentley's efforts, the Justice Department last May released to states a list of 479 drugs that the department said had inflated AWPs. A partial copy of the list obtained by Stateline.org shows that:

- Adriamycin, an antibiotic used in cancer treatment and manufactured by Pharmacia, had an AWP of \$241.36 as of April 2000. DOJ said the real wholesale price was \$33.43.
- Amikacin, used to treat an infection that HIV+ people get and manufactured by Abbott, had an AWP of \$54.56. DOJ said the actual best price was \$6.75.
- Toposar, also manufactured by Pharmacia, is used to treat testicular and lung cancer. Its AWP as of April 2000 was \$28.38; DOJ found that retailers were buying it for \$1.70.
- Vancomycin, an antibiotic used to treat intestinal infections and manufactured by Abbott, had an AWP of \$68.77 as of April 2000. DOJ adjusted it to \$8.14.

Bentley says that the AWP "is only part of" the price inflation controversy. "There's a whole area of questionable conduct and questionable areas manufacturers have used," he says.

Congressman Pete Stark (D-CA) wrote letters to PhRMA President Alan Holmer last fall and to Pharmacia Upjohn, Bristol-Meyers Squibb and Abbott on Feb. 27, alleging among other things, "the exploitation of America's seniors and disabled who are forced to pay inflated drug costs."

In a five-page letter to Bristol-Meyers Squibb president Peter Dolan, Stark alleges there is "compelling evidence that Bristol-Meyers Squibb ('Bristol') for many years deliberately overstated the prices of some of its prescription drugs in order to cause the Medicare and Medicaid programs to pay inflated amounts to Bristol's customers."

Stark's letter also contains a chart that details an alleged spread between the AWP and actual price to Florida oncologists for the drug Blenoxane. In 1995, the AWP was \$276.29 but oncologists were charged \$224.22, for a spread of \$52.07. In 1998, the AWP was listed at \$304.60; the price charged to doctors was \$140 for a spread of \$164.60.

Florida's Schlein says abuse is widespread. "The whole area of prescription drug fraud is incredibly important and involves virtually every manufacturer. It involves nothing less than a conspiracy among manufacturers, middlemen and doctors who prescribe [the drugs]. The bottom line is everyone is doing this with a nod and a wink and [taxpayers] are paying for it," he says.

Other state officials have voiced similar concerns. Georgia Department of Community Health director Russ Toal said at a Medicaid forum in February that his state has reason to believe that pharmaceutical manufacturers are overcharging Medicaid programs. "We've sent some evidence of that to both the Health Care Financing Administration and the Department of Justice, and I hope that other states are doing the same," he said.

Former Maine Attorney General Andrew Ketterer says "the area [of AWP] is fertile for attorneys general to look into. Pharmaceutical companies spend a fair amount of money on research and development for wells that don't have oil and they have to recover from those losses in some way. [A lawsuit] is not out of the range of possibilities that would come on to the radar screen. It's an area that is of great interest to a lot of people."

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing Memorandum of the Attorney General of the Commonwealth of Pennsylvania in Opposition to Class Certification was served on all counsel of record by electronic service pursuant to Case Management Order No. 2.

Dated: February 8, 2005

Respectfully submitted,

Louis C. Ricciardi, Esquire

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